INSTRUCTIONS FOR USE

General Product Identification Information

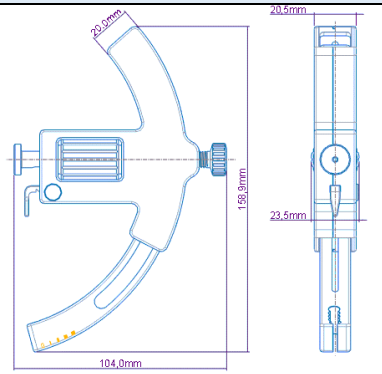
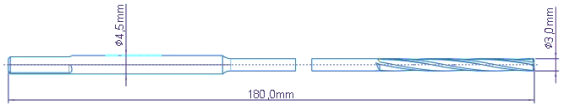
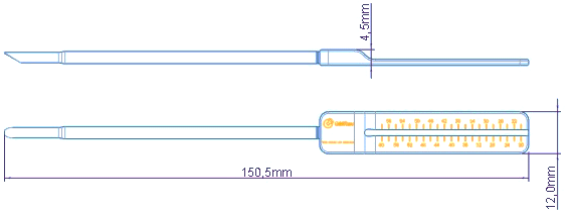
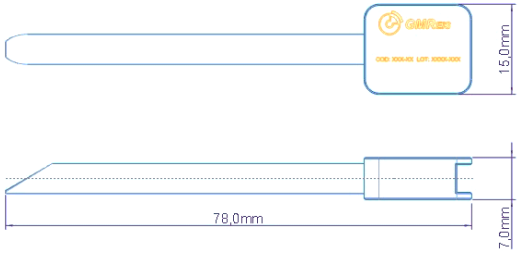
Non-implantable product, reusable, subject to reprocessing, supplied non-sterile – sterilize before use according to the recommended sterilization method.
The implantable components are not object of this registration.

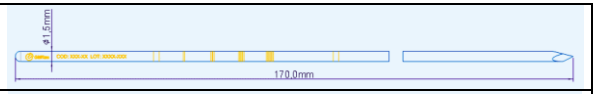
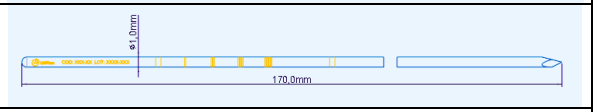
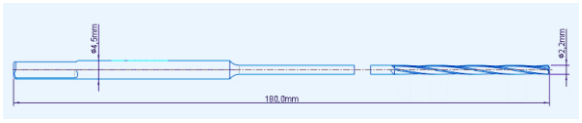
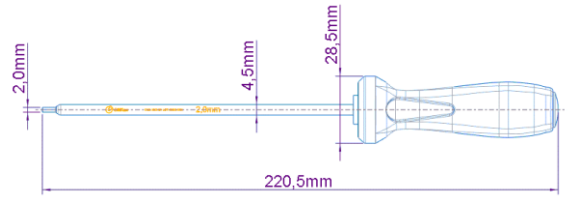
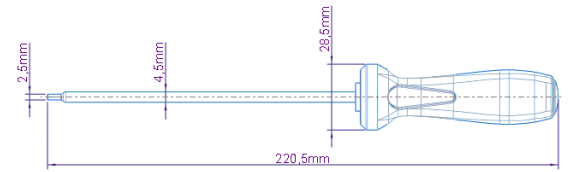
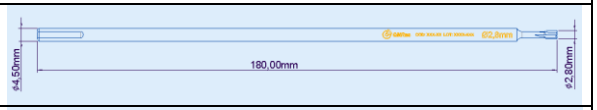
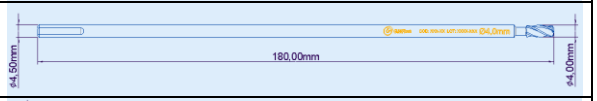
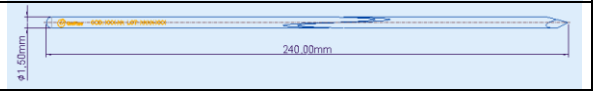
1. Information necessary for the user to identify the product and its content

1.a. Technical Name: Orthopedic manual surgical instrument
1.b. Trade Name: MICA Guide

1.c. Graphic information that allows the visualization of the final product, description, part number and composition of the material

Table 1: Graphic images (photos or drawings) of the product, its accessories, and parts, with their respective identification codes and technical description of the raw material:

CODE	DESCRIPTION	DIMENSION	IDENTIFICATION OF SPECIFIC USE	RAW MATERIAL	PICTURE
362-10	GUIDE	23.5x104.0x159.0mm	PERFORM THE CONTROLLED TRANSLATION OF THE METATARSAL HEAD IN THE CORRECTION OF THE HALLUX VALGUS AND GUIDE THE DRILLING OF THE SCREWS THAT WILL FIX THE OSTEOTOMY	STAINLESS STEEL ASTM F899/ POLIACETAL ASTM F1855-00 / ALUMINUM ISO 6834	
362-11	HELICAL CANNULATED DRILL	Ø3.0xØ1.8x180.0mm	PERFORM THE BONE HOLE PERFORATION IN WHICH A METALLIC SCREW WILL BE IMPLANTED	STAINLESS STEEL ASTM F899	
362-12	MICA GUIDE DEPTH GAUGE	4.5x12.0x150.5mm	PERFORM THE BONE DEPTH MEASUREMENT IN THE REGION WHERE A METAL SCREW WILL BE APPLIED USING A GUIDE WIRE AS A REFERENCE	STAINLESS STEEL ASTM F899	
362-13	MICA GUIDE CANNULA	7.0x15.0x78.0mm	GUIDE THE APPLICATION OF THE DRILL AND THE GUIDE WIRE	STAINLESS STEEL ASTM F899	

362-14	GRADUATED GUIDE WIRE Ø1.5x200.0mm	Ø1.5x200.0mm	GUIDE THE ASSEMBLY OF THE MICA GUIDE	STAINLESS STEEL ASTM F899	
362-15	GRADUATED GUIDE WIRE Ø1.0x240.0mm	Ø1.0x240.0mm	GUIDE THE DRILLING AND APPLICATION OF THE METAL SCREW	STAINLESS STEEL ASTM F899	
362-16	HELICAL CANNULATED DRILL Ø2.2xØ1.2x180.0mm	Ø2.2xØ1.2x180.0mm	GUIDE THE DRILLING AND APPLICATION OF THE METAL SCREW	STAINLESS STEEL ASTM F899	
362-17	MICA CUT SCREW HEX WRENCH - Ø2.0mm	220.5x28.5x4.5xØ2.0 mm	GUIDE THE APPLICATION OF THE METAL SCREW	STAINLESS STEEL ASTM F899/POLIACETAL ASTM F1855-00	
362-18	MICA CUT SCREW HEX WRENCH - Ø2.5mm	220.5x28.5x4.5xØ2.5 mm	GUIDE THE APPLICATION OF THE METAL SCREW	STAINLESS STEEL ASTM F899/POLIACETAL ASTM F1855-00	
362-20	CANNULATED REAMER Ø2.8	Ø4.5 x Ø2.8 x 180.0mm	PERFORM DRILLING IN THE PERFORATION CREATED BY THE DRILL	STAINLESS STEEL ASTM F899	
362-21	CANNULATED REAMER Ø4.0	Ø4.5xØ4.0x180.0mm	PERFORM DRILLING IN THE PERFORATION CREATED BY THE DRILL	STAINLESS STEEL ASTM F899	
362-22	GUIDE WIRE	Ø1.5x240.0mm	GUIDE THE DRILLING AND APPLICATION OF THE METAL SCREW	STAINLESS STEEL ASTM F899	

1.d. Detailed description of the medical product, including the fundamentals of its operation and action, its content and/or composition

The Mica Guide was specially designed for distal or proximal osteotomies procedures in cases of symptomatic Hallux Valgus deformities.

1.e. How Supplied

Products are supplied non-sterile, duly identified, that is, laser marked with their code, batch number and GMReis logo. Its form of commercial presentation is the packaging of instruments in a specific box, packed in polyethylene/polyester plastic and labeled. Instruments are individually packaged and are also properly labeled. The set of Instruments consists of 1 unit of each item. In case of replacement, the items in the set may be sold separately. A manual is included with the product on how the user can obtain the Instructions for Use of the product, in non-printed format, at no additional cost, including shipping. This information is compatible with the product labeling.

Technical packaging specification: Polyethylene/polyester plastic packaging (tubular structure or envelope).

1.f. Physical principle and fundamentals of its technology and its action

The Mica Guide was specially designed for distal or proximal osteotomies procedures in cases of symptomatic Hallux Valgus deformities.

These are reusable and resterilizable products.

These surgical instruments have functions such as: guiding, drilling, reaming and measuring the depth of the perforation.

1.g. Composition of instruments manufacturing materials:

The instruments can be manufactured with different raw materials that are selected according to the function of the instrument..

Stainless Steel - ASTM F899
Aluminum - ISO 209
Polyacetal - ASTM F1855

1.h. Identification

Products are laser marked with the following information:

- Product Batch
- Product Code
- GMReis Logo
- Size (When applicable)

Product identification is ensured through the Instruction for Use, bringing information about the product, such as: name, model, code, batch, product registration and manufacturer identification.

PORTUGUÊS (PT)	ENGLISH (EN)	ESPAÑOL (ES)	
A Instrução de Uso para este produto está disponível no website www.gmreis.com.br/produtos/IFU, (formato não impresso) e sempre estará de acordo com a última versão vigente, aprovada pela Anvisa	The Instruction for USE (IFU) for this product is available on the website: www.gmreis.com.br/produtos/IFU (printed format) and will always be in accordance with the latest version, approved by Anvisa	La Instrucción de Uso para esto producto está disponible en el sitio web: www.gmreis.com.br/produtos/IFU (formato impreso) y siempre será con arreglo a la última versión en vigor, aprobado por la Anvisa	GMREIS Qualidade para Vida
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Figure: Manual that comes with the product.

1.2. Storage, conservation, handling, transport, and associated risks

The product must be handled, preserved, stored, and transported in such a way as to prevent any damage or alteration to its characteristics and packaging.

The medical product must be handled with great care, in order to avoid sudden shocks, falls and other risks and/or imperfections that affect its quality and user safety.

It must be preserved and stored in its original packaging, until the time of use, in a clean, dry, airy environment, protected from sunlight, free of contaminating substances (acid and organic vapors), and with temperature and humidity control.

Handling and storage of the product must be carried out exclusively by professionals in the medical-hospital area, duly trained, qualified and familiar with the technique and procedures involved.

The effects of vibration, shocks, faulty seating, improper stacking, and temperature above 45°C during transport must be avoided.

The storage, handling, conservation, and transport of the product outside the specified conditions can generate risks to the procedure and to the patient.

1.3. Instructions for using the product

The Mica Guide was specially designed for distal or proximal osteotomies procedures in cases of symptomatic Hallux Valgus deformities.

The instruments are used by a surgeon whose surgical technique to be adopted by him is part of his professional training.

The instruments are variable in terms of shape and dimensions, and the professional responsible for the procedure is responsible for deciding where and how to use the instruments, as well as deciding on the type, shape, and dimensions.
These products can be reused but must not be bent or shaped in any way.

1.4. Precautions, restrictions, warnings and special care and clarification on the use of the product, as well as its storage and transportation

Reusable, non-sterile product, perform pre-use procedures and send to sterilize before use.

The instruments must be used according to specific surgical techniques adopted by a duly trained professional qualified in distal or proximal osteotomies procedures in cases of symptomatic Hallux Valgus deformities.
Extreme care must be taken to ensure that the surgical instrument remains in good working condition. Any surgical techniques applicable to the use of this system must be carefully followed. During the procedure, it is extremely important to use the surgical instrument correctly. This instrument can be reused but must not be bent or damaged in any way. Misuse of the surgical instrument may cause corrosion, loosening, bending and/or fracture of any or all sections of the surgical instrument, which may inhibit its proper functioning.
Do not use this instrument for any action it was not designed for such as leveraging, lifting weights, etc. Surgical instruments must be treated like any other precision instrument and must be carefully packed in surgical trays, cleaned after each use, and stored in a dry, weather-free environment.
Only sterile instruments should be used in surgery. Surgical instruments must be thoroughly cleaned, dried, and disinfected with appropriate agents before resterilization.
The improper use of surgical instruments as well as the use of damaged surgical instruments can cause injury or damage to the patient or the operating room staff, for example, incorrect use can cause breakage and penetration of pieces or components into the patient or someone who is around. If it is damaged, do not reuse it, replace it.
Care in distribution, storage, transport, cleaning, storage, conservation, and traceability must follow the Good Practices for Storage and Distribution of Medical Products, in accordance with the current resolution. Surgical instruments should be stored in a dry, airy, clean place, free from the action of the weather, and at room temperature.

2. Indication, purpose or use for which the product is intended

The Mica Guide was specially designed for distal or proximal osteotomies procedures in cases of symptomatic Hallux Valgus deformities.

2.a. Undesirable effects or side effects and contraindications

Not applicable.

2.b. Contra Indications

The use of the product is contraindicated for any procedure other than distal or proximal osteotomies in cases of symptomatic Hallux Valgus deformities.

3. Detailed information on the characteristics of all parts, accessories and materials intended for use with the product

3.1. Permissible combinations with other implantable components

Instruments should only be used for distal or proximal osteotomies in cases of symptomatic Hallux Valgus deformities. If any other surgical instruments are used together with those that make up the Mica Guide, risks may be generated for the patient and/or procedure, being the responsibility of the professional responsible for the surgical procedure.

4. Information that makes it possible to verify whether the installation was correct and safe, as well as information regarding the nature and frequency of evaluations to be carried out in order to guarantee the permanent good functioning and safety of the product

After cleaning and disinfection carried out after use, all instruments must undergo a technical inspection to ensure that they are working properly. If the inspected product is non-compliant, that is, it does not present itself in perfect working conditions, corrective action must be taken to remove and replace the non-compliant product with another GMReis brand with the same characteristics and function.

5. Additional information on proper reuse procedures

Surgical instruments are reusable and resterilizable products. Before sending for sterilization as described in the Sterilization Method item, follow the cleaning, disinfection, packaging, and technical inspection instructions described in the following items, in order to guarantee safety in its reuse**.**

There are no restrictions on the possible number of reuses, as long as the product is in perfect condition and has been submitted to technical inspection.

5.a. Sterilization Method

Surgical instruments must be sterilized according to the method described in the specification below:

Method: Moist Heat

Cycle: Gravity

Temperature: 121ºC (250ºF)

Exposure time: 30 minutes

Additional information regarding sterilization is described in ISO 17665-1-“Sterilization of Health Products – Steam. Part 1: Requirements for the development, validation, and routine control of sterilization processes for medical devices”.

5.b. Packaging - Final assembly

After the technical inspection, the surgical instruments must be packed and assembled in specific surgical trays and boxes, and then sent for sterilization according to the Sterilization Method described.

5.c. Disposal

Non-compliant instruments, or those that are out of use conditions, must be segregated, discarded, and replaced by others of the GM Reis brand that have the same characteristics and function. All discarded surgical instruments must be disposed of with twisters or molders to avoid future misuse.

After being unusable, the product must be discarded according to the procedure of the medical-hospital area or regional legislation or according to the Instructions of the Hospital Infection Control Commission - CCIH.

5.d. Restrictions regarding the occurrence of product fall

If the product falls, the product must be returned to GMReis.

5.e. Notice regarding damage to the original packaging

If the original packaging of the product is damaged or violated, the product must be returned to GMReis and must not be used.

6. Specific guidelines for the physician regarding the reporting of adverse events and technical complaints

If the product presents adverse events not reported in the instruction of use or has technical complaints about the product, the surgeon should immediately contact the manufacturer through the Customer Service (SAC) of GM Reis, in addition to notifying the competent health authority.

To ensure traceability of the product, the surgeon should proceed according to the "product traceability procedure". Product traceability is ensured through the 5 traceability labels provided inside the package, together with the product, as described in the item "Product Traceability Procedure".

7. Customer Complaint

If the medical product presents a specific unpredictable risk, is out of its specifications or is generating any dissatisfaction, notify GM Reis Customer Service (SAC) directly. The product should be forwarded clean and packed in a plastic bag, duly identified and with the description of non-conformity to the following address: **Av. Pierre Simon de Laplace, 600 - Lote 3 - Quadra F - Block 9677 - ZIP Code 13069-320 - Condominium Technopark - Campinas, SP, Brazil or notify directly at Tel.: (0XX19) 3283-9020; E-mail: sac@gmreis.com.br.**

8. Symbology of Labelling

The graphic symbols used in the labeling are in accordance with the ISO 15223 Standard as follows:

Symbol	Description	Symbol	Description
	Date of Manufacture		Do not reuse
	Manufactured by		Batch number
	Use-by date		Caution “see instructions for use”
	Keep dry		Keep away from sunlight
	Prescription use only		Do not use if package is damaged
	Non-sterile		Product catalogue number

ALERT TO THE CUSTOMER

These Instructions for Use are made available in unprinted format, through the manufacturer's e-mail address: http://www.gmreis.com.br/produtos/IFU. *Always check the correlation of the Version of the Instructions for Use with the version reported on the label.* The instructions for use provided will always be in accordance with the latest version in force. If the user is interested, the Instructions for Use may be made available in printed format at no additional cost. Request for free by e-mail: sac@gmreis.com.br.

GM dos Reis Indústria e Comércio Ltda.
Pierre Simon de Laplace Avenue, nº 600 - Lot 3 - Block F - 9677
Nova Aparecida Neighborhood
TECHNOPARK - ZIP Code: 13069-320 – Campinas – SP - BRAZIL
Operating permit – AFE n° 1.02.477 - 0
C.N.P.J/M.F: 60.040.599/0001-19 / I.E: 244.342.283.119
E-mail: gmreis@gmreis.com.br
Phone.: (0XX19) 3765-9900
Issuing date: 03/06/2023

Technical and Legal Responsible Qualified:

Geraldo Marins dos Reis Júnior
CREA - SP N° 0682127536

Revisions History
Rev.00 03/06/2023 - Initial
Rev.01 06/15/2023 - Device Listing in USA